PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

TicoVac® 0.5 ml, suspension for injection

Each dose (0.5 ml) contains 2.4 micrograms of whole inactivated *Tick-Borne Encephalitis Virus*

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

TicoVac 0.5 ml is an active vaccine intended to prevent a disease caused by the *Tick-Borne Encephalitis Virus*. The vaccine is intended for adolescents from the age of 16 and adults.

The vaccine causes the body to produce antibodies against the virus. It does not protect against other viruses and bacteria (some of which are also transmitted by tick bites) that may cause similar symptoms.

Therapeutic group: Encephalitis vaccine

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You or your child are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in this medicine (listed in section 6). For example, you or your child had a rash, swelling of the face or throat, difficulty in breathing, blue discoloring of the tongue or lips, low blood pressure and have collapsed. Pay attention to cross-sensitivity with aminoglycosides aside from neomycin and gentamycin.
- You or your child had a severe allergic reaction after eating eggs or chicken.
- You or your child have a moderate or severe acute illness (with or without fever). Delay the vaccination.

Special warnings regarding use of the medicine

Before treatment with TicoVac, tell your doctor if:

- You or your child have bleeding problems or bruise easily
- You or your child have an autoimmune disease (such as rheumatoid arthritis or multiple sclerosis)
- You or your child have a weak immune system (so that you or your child do not fight infections well)
- You or your child do not produce antibodies well
- You or your child are taking medicines for cancer
- You or your child are taking medicines called corticosteroids (reduce inflammation)

- You or your child have any brain illness
- You or your child have a neurological disorders or seizure disorders

The vaccine may not be suitable, if any of the circumstances above apply to you or your child. Alternatively, the doctor may decide to give you or your child the vaccine. The doctor may request to do a blood test to check whether the vaccine has worked.

Children and adolescents
Do not give this vaccine to children under 16 years of age. This age group should be given the TicoVac Junior 0.25 ml vaccine, which is intended for children.

Drug interactions
If you or your child are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

If you or your child have recently received another vaccine, the doctor will decide where and when to give the TicoVac vaccine.

TicoVac may not provide complete protection If you or your child are under an immunosuppressive treatment.

Tell the doctor if you or your child have been infected with, or been vaccinated against, Yellow fever, Japanese encephalitis or Dengue fever. This is because you or your child may have antibodies in the body that can react with the *Tick-Borne Encephalitis Virus* used in tests to measure the antibody levels in your body. These tests could then give wrong results.

Pregnancy and breastfeeding
If you or your child are pregnant or breastfeeding, think that you or your child are pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before receiving the vaccine. Your doctor will discuss with you or your child the possible risks and benefits. The effect of TicoVac during pregnancy or while breastfeeding is not known. However, the vaccine may still be given if the risk of infection is high and after consideration of benefit versus risk.

Driving and using machines
The vaccine is not expected to affect ability to drive or operate machines. However, you or your child may have problems with your sight or feel dizzy.

Important information about some of this medicine's ingredients
The preparation contains potassium and sodium at levels of less than 1 mmol per dose, that is to say essentially 'potassium- and sodium-free'.

3. HOW TO USE THIS MEDICINE?
Always use this medicine according to your doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by your doctor only.

This vaccine is usually injected into the muscle of the upper arm. The vaccine must not be injected into a blood vessel. In exceptional cases only (if you or your child have bleeding problems or are receiving anticoagulants for blood thinning), the vaccine may be administered under the skin (subcutaneously).

Do not exceed the recommended dose.

If you have accidentally taken a higher dosage
Since the injection is given via a pre-filled syringe that contains a single dose, an overdose is highly unlikely to happen.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.

If you have further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of TicoVac may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

As with all vaccines, severe allergic reactions can happen. They are very rare, but immediate medical treatment and supervision are required. Symptoms of serious allergic reactions include:

- Swelling of the lips, mouth, throat (which may make it difficult to swallow or breathe)
- A rash and swelling of the hands, feet and ankles
- Loss of consciousness due to a drop in blood pressure.

These signs and symptoms usually happen very quickly after the injection, while the person is still in the clinic. If any of these symptoms happen after you leave the place where your injection was given, refer to a doctor immediately.

Additional side effects:

Very common side effects (may affect more than 1 in 10 users):

- Pain at the injection site.

Common side effects (may affect up to 1 in 10 users):

- Headaches
- Nausea
- Muscle and joint pains
- Feeling tired or unwell.

Uncommon side effects (may affect up to 1 in 100 users):

- Swelling of lymph glands
- Vomiting
- Fever
- Bruising at the injection site.

Rare side effects (may affect up to 1 in 1,000 users):

- Allergic reactions
- Sleepiness
- Motion sickness
- Diarrhea
- Abdominal pain
- Redness, tissue hardening, swelling, itching, tingling and warmth at the injection site.

Additional side effects with a rare frequency that were reported from post marketing surveillance of the preparation:

- Shingles
- Triggering of autoimmune diseases such as multiple sclerosis
- Allergic reactions
- Neurological disorders such as encephalomyelitis, inflammation of the spinal cord
- An illness involving muscle weakness, abnormal sensation, tingling in the arms, legs and upper body (Guillain-Barré syndrome)
- Inflammation of the brain, fits, inflammation of the meninges
- Signs of meningeal irritation, like pain and stiffness of the neck
- Neurological symptoms such as facial palsy, paralysis, inflammation of nerves, abnormal or reduced sensation such as tingling or numbness, stabbing or throbbing pain along one or more nerves, inflammation of the visual nerve
- Feeling dizzy
- Visual disorders, being more sensitive to light, pain in the eye
- Ringing in the ears
- Rapid beating of the heart
- Shortness of breath
- Skin reactions (rashy and/or itchy skin), dermatitis, redness of the skin, increased sweating, inflammation of the skin
- Back pain, joint swelling, neck pain, musculoskeletal and neck stiffness, pain in hands and legs
- Chills, influenza-like illness, weakness, edema, unsteady walking, accumulation of fluid beneath the skin
- Joint pain at the injection site, nodules and inflammation at the injection site.

In a small comparative study on the immune response after intramuscular and subcutaneous administration of TicoVac in healthy adults, subcutaneous administration caused more local reactions at the injection site (e.g., redness, swelling, itching and pain), especially in women.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects, or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C-8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.
- Do not use the vaccine if you notice foreign particulate matter or leakage.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
Sodium chloride, human serum albumin, aluminium hydroxide (hydrated), disodium phosphate-dihydrate, potassium dihydrogen phosphate, sucrose, formaldehyde, protamine sulfate, neomycin and gentamicin, water for injection

What the medicine looks like and contents of the pack:
TicoVac is marketed as a suspension (0.5 ml) for injection in a pre-filled syringe. The package contains 1, 10, 20 or 100 pre-filled syringes. Not all pack sizes may be marketed. The package may contain a needle. The needles are sterile and are intended for single use.

Each pre-filled syringe is packaged in a blister pack. The opening in the blister pack is intended and allows for the equilibration of moisture during the vaccine incubation time until it reaches room temperature. Open the blister by removing the lid to take out the syringe. Do not press the syringe through the blister pack.

After shaking, the suspension is off-white and milky.

Registration holder and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
162-33-35413

Revised in 11/2023 according to MOH guidelines.

The following information is intended for medical or healthcare professionals only:
The vaccine should reach room temperature before administration. Shake well prior to administration to thoroughly mix the vaccine suspension.
After shaking, TicoVac 0.5 ml is an off-white, opalescent, homogeneous suspension.
The vaccine should be inspected visually for any foreign particulate matter and/or variation in physical appearance prior to administration. In the event of either being observed, discard the vaccine.
After removing the syringe cap, attach the needle immediately and remove the needle shield prior to administration. Once the needle is attached, the vaccine must be administered immediately.
In the exceptional cases of subcutaneous administration, an appropriate needle should be used.
Any unused product or waste material should be disposed of in accordance with local requirements.